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Update on the Philippine Biotechnology Situation

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Report Highlights:

The Philippine biotechnology regulatory system continues to evolve but remains science-based. The approval registry for the importation of regulated articles for direct use for food, feed and for propagation continues to grow and a low level presence policy that is consistent with the Codex Plant Guidelines has been adopted this year. Commercialization of the first genetically enhanced crop developed locally will be delayed, and will likely be commercially available by 2013.

Section I. Executive Summary:

The Philippine biotechnology regulatory system is evolving and the country remains to be a consistent and strong supporter of science-based modern agricultural biotechnology. Early this year, the Philippine Department of Agriculture (DA) adopted Annex 3 to the Codex Plant Guideline, i.e., “Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food”, for the conduct of food safety assessment in situations of low-level presence of recombinant-DNA plant materials in food and feed. The low-level presence policy is expected to minimize trade disruptions as a result of GE traces in food and feed grain shipments to the Philippines.

Under the current regulatory regime provided for under the DA's Administrative Order No. 8 (DA-AO 8), 30 transformation events (TEs) and 18 combined or stacked trait products have been approved for direct use as food, feed or propagation. There are currently four (4) biotech crop varieties approved for propagation while there have been nine (9) field tests approved since 2004. Guided by DA-AO 8, the first genetically enhanced (GE) crop being developed locally will likely be commercialized by early 2013.

While the overall national Philippine policy is very supportive on the responsible use of modern agricultural biotechnology, there remain pockets of resistance in some local government units (LGUs). The latter is being appropriately addressed by the DA's outreach program.

Section II. Biotechnology Trade and Production:

A key market in Southeast Asia for U.S. agricultural, fish and forestry exports, export sales to the Philippines reached over \$1.77 billion in 2008, the highest level ever. The top U.S. exports last year were wheat (\$703 million), soybean and soybean meal (\$270 million), dairy products (\$210 million), processed fruits and vegetables (\$55 million) and snack foods (\$50 million). Total U.S. agricultural, fish and forestry exports rose 53 percent in 2008 compared to the 2007 level due to rising commodity prices, the stable Philippine peso and sustained efforts of FAS Manila to expand U.S. agricultural sales. The United States remains the top food and beverage supplier to the Philippines although competition with products from Australia, New Zealand, the EU, Canada, China, and the ASEAN has remained strong.

The following table illustrates U.S. exports to the Philippines last year that possibly were derived from modern agricultural biotechnology. Trade value was approximately \$354 million dollars with soybean meal and corn-based feed accounting for the majority share (84 percent). Biotechnology trade in the coming years is expected to be enhanced by the adoption of an internationally accepted low-level presence policy by the DA (see BIOTECHNOLOGY POLICY).

2008 Biotechnology Trade to Philippines
(In Thousands of Dollars)

Biotechnology Commodity	Philippines	% Share
Soybean Meal	243,918	69.00
Feeds & Fodders	53,026	15.00
Soybeans	26,347	7.00
Sweeteners	15,751	4.00
Cotton	8,360	2.00
Vegetable Oil	4,756	1.00
Soybean Oil	1,048	0.30

Coarse Grains	802	0.23
TOTALS	354,008	100.00

Source: BICO

The number of TEs approved for commercial production or propagation remains unchanged from the previous annual report's level at three (3), namely: Monsanto's Corn MON810, Corn NK 603, and Syngenta's Corn Bt 11 (see Appendix A). In addition to the approved TEs, one (1) stacked or combined trait corn variety (Corn MON810 x Corn NK603) comprises the 4 biotech crop varieties approved for propagation.

In 2008, the Philippine Bureau of Plant Industry (BPI) estimates the total area planted to GE corn at 317,923 hectares, slightly higher than the 313,910 hectares planted in 2007. Excessive rainfall last year discouraged corn cultivation with overall corn output and area harvested in 2008 declining from the previous year's level. This year, GE corn seed use may decline from the previous year's level due to continued rainfall as well as the removal by the DA its seed subsidy for corn hybrids, including GE corn. Corn hybrid seeds used to be subsidized at a rate of P1,200 per bag per hectare (\$25). The funds for the seed subsidy program reportedly will be rechanneled to farm infrastructure instead.

The latest list of regulated articles approved for field testing, based on BPI data, is provided in the following table. Since 2004, 9 GE crop field trials have been approved, for a slight increase from the six (6) approved field tests reported in the previous annual report.

APPROVAL REGISTRY FOR FIELD TESTING of REGULATED ARTICLES as of January 26, 2009		
Proposal	Technology Developer	Date Approved
1. Demonstration of Weed Control Performance of Roundup Ready Corn (RRC) System (DK818 NK603) vis-à-vis Farmers' Practices	Monsanto	11/26/04
2. Performance of Roundup Herbicide (360 g ae/L IPA Salt (Against Weeds in Glyphosate-Tolerant Corn	Monsanto	11/26/04
3. Field Verification of the Agronomic Performance of the Transgenic Corn Hybrid Stacked (NK603/MON 810) Expressing the Bacillus Thuringiensis Cry1AB Protein for Resistance Against the Asiatic Corn Borer and CP4 EPSPS for Tolerance Gainst the Herbicide Roundup	Monsanto	12/10/04
4. Performance of Heculex 1 Bt Trans-	Dow Sciences	05/02/06

genic Corn Hybrids against Asiatic Corn Borer Under Field Conditions in the Philippines.		
5. Field Testing of Transgenic Papaya w/ Delayed Ripening Trait	IPB-UPLB	03/20/07
6. Multi-locational Field Efficacy Verification Trial of Herbicide Tolerant Maize Expressing Event GA21 Against Glyphosate Herbicide in the Philippines.	Syngenta	11/19/07
7. Agronomic Equivalency Trial of MON89034 Hybrids w/ Regulatory Framework in the Philippines	Monsanto	08/01/08
8. Field Verification of the Agronomic Performance of Transgenic Corn Line MON89034 Expressing the Bacillus thuringiensis Cry1AZ.105 and Cry2Ab Proteins for Efficacy Against Lepidopterous Pests of Corn.	Monsanto	08/01/08
9. Field Verification of the Agronomic Performance of Stacked Hybrid Corn MON89034 x NK603 Expressing the Bacillus Thuringiensis Cry1A.105 and Cry2Ab2 Proteins for Efficacy against Lepidopterous Pests of Corn and CP4EPSPS for Tolerance of Round up Herbicide for Field Testing.	Monsanto	08/01/08

Source of Basic Data: Bureau of Plant Industry

The fruit and shoot borer resistant (FSBR) eggplant project of the Institute of Plant Breeding, University of the Philippines in Los Banos and the golden rice project of the Philippine Rice Research Institute (PhilRice) mentioned are still under the supervision of the National Committee on Biosafety of the Philippines. The former is currently undergoing efficacy verification and is scheduled for multi-location trials this year through 2010. The earliest time the FSBR eggplant will be available for commercial release will likely be in 2011, and not this year as previously projected. It is expected to be the first locally developed GE crop by the Philippines. Following the FSBR eggplant, projected to be commercialized also by 2011 is the transgenic papaya with a delayed ripening trait.

Developments in the golden rice project, on the other hand, are expected to delay its commercialization from 2010 to 2013. According to PhilRice contacts, the golden rice being developed now is expected to carry more beta-carotene than earlier projected.

Section IV. Biotechnology Policy:

The more than 7,000 islands which comprise the Philippines are classified under three major island groups: Luzon, Visayas and Mindanao. There are 16 administrative regions covering about 81 provinces. Overall, the country has an estimated 136 cities and 1,454 municipalities.

In the early 1990s, the Local Government Code of 1991 was enacted to provide meaningful autonomy to LGUs. The law called for the decentralization of certain national functions to LGUs including agricultural extension. It likewise establishes the system and powers of provincial, city, municipal and local village governments in the Philippines and empowers LGUs to enact local regulations including tax measures and the adoption and acceptance of GE plants and products. While overall Philippine policy has been very supportive, things are not always the same at the local level (see MARKETING).

In general terms, however, as the first Asian country to approve the planting of a biotechnology food crop, the country remains to be a consistent supporter of rational, science-based regulations. The Philippines recently adopted Annex 3 to the Codex Plant Guideline, i.e., “Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food”, for the conduct of food safety assessment in situations of low-level presence of recombinant-DNA plant materials in food and feed. This is embodied in the DA’s Administrative Order No. 1 (AO No. 1) Series of 2009. With the increasing global trade and movement of GE and GE-derived food products, DA-AO No. 1 will minimize trade disruptions as a result of low-level presence or minimal GE traces in grain shipments. Less trade disruptions will likely enhance the food security position of the Philippines being a net importer of food and feed grains (rice, corn, wheat and soybeans).

The responsible GRP regulatory agencies and their roles in relation to Philippine biotechnology regulations remain unchanged compared to the previous annual report. Under DA-AO8, 30 TEs have been approved for food, feed or processing materials (see Appendix A), higher than the 28 approved TEs reported in the previous annual report.

In addition, there were approved 18 stacked trait products as of January 26, 2009, unchanged from the previous annual report (GAIN 8043). A summary follows:

SUMMARY OF APPROVED COMBINED TRAIT PRODUCTS				
as of January 26, 2009			Interaction of Resulting Gene Products	
Combined Trait Product	Technology Developer	Date Approved	Yes	No
1. Corn MON810 x Corn NK603*	Monsanto	11/16/04 07/19/05		X
2. Corn NK603 x Corn MON863	Monsanto	11/16/04		X
3. Corn MON810 x Corn MON863	Monsanto	11/16/04		X
4. Corn MON810 x GA21	Monsanto	11/16/04		X
5. Cotton 531 x Cotton 1445	Monsanto	11/22/04		X
6. Cotton 15985 x Cotton 1445	Monsanto	11/22/04		X

7. Corn MON863 x MON810 x Corn NK603	Monsanto	02/07/05		X
8. Corn TC 1507 X Corn NK603	Pioneer	02/17/06		X
9. Cotton 15985 x Cotton 88913	Monsanto	04/20/06		X
10. Corn MON 88017 x Corn MON 810	Monsanto	07/03/06		X
11. Corn LY038 x Corn MON810	Monsanto	08/09/06		X
12. Corn DAS 59122 x Corn NK603	Pioneer	12/20/06		X
13. Corn Bt 11 x Corn GA21	Syngenta	01/23/07		X
14. Corn TC1507 x Corn DAS 59122	Pioneer	01/23/07		X
15. Corn DAS59122 x Corn TC1507 x Corn NK603	Pioneer	02/07/07		X
16. Corn Bt11 x Corn MIR 604	Syngenta	12/13/07		X
17. Corn MIR 604 x Corn GA21	Syngenta	12/13/07		X
18. Corn Bt11 x Corn MIR 604 x GA21	Syngenta	03/03/07		X

* Approved for propagation

Source of Basic Data: Bureau of Plant Industry

Section V. Marketing:

As mentioned in p. 8 of GAIN 6026, despite a very positive policy statement issued by President Gloria Macapagal-Arroyos on the responsible use of modern agricultural biotechnology, “some LGUs have either been lukewarm to the technology or have imposed outright bans on the propagation of biotech crops in their respective areas.” One such area is the province of Negros Occidental in the Visayas region which has an existing ban on the entry of GE plants and animals. Sometime early April this year, provincial authorities seized a shipment of locally produced GE corn worth about P19 million (US\$400,000). While the owner of the GE corn (a feedmilling company) agreed to ship out of the province the GE corn, a Philippine hog industry association leader objected warning that that the province would suffer from a shortage in animal feed if the corn were shipped out. The same industry official reportedly also warned that provincial hog and poultry raisers would put on hold all expansion programs in the province should the ban stay on.

The Negros Occidental provincial board early this month reportedly approved a review of the GE ban although the ordinance would stay in effect pending results of the evaluation. Negros Occidental’s main agricultural produce is sugar, and several sugar industry groups have also supported for a review of the existing ban.

Meanwhile, the Provincial Veterinary Office (PVO) reportedly has submitted to the Negros Occidental LGU a project proposal worth P213.74 million (\$4.45 million) to establish a GE laboratory capable of detecting GE plants and animals. The project was based on a quotation from the Assure Quality Laboratory (AQL) in Auckland, New Zealand, according to press reports.

Regarding Bayer’s Rice LL62, there has been no progress in its deregulation as the temporary restraining order (TRO) imposed by a local court continues to prevent the BPI from moving forward (refer to GAIN 7057).

Section VI. Capacity Building and Outreach:

Isolated resistance to the adoption and acceptance of GE products from Philippine LGUs continues to be part of the DA's biotechnology outreach program.

In general terms, the biotechnology and biosafety short courses offered by the Michigan State University under the COCHRAN Fellowship Program continues to be the primary USDA biotechnology capacity building activity for Philippine regulators, technical personnel and policy makers.

Section VII. Author Defined:

APPENDIX A

APPROVAL REGISTRY FOR THE IMPORTATION OF REGULATED ARTICLES FOR DIRECT USE FOR FOOD, FEED & FOR PROPAGATION						
As of January 26, 2009			Safety Assessment			
Event	Introduced trait and gene	Date Approved	Food	Feed	Propagation	Developer
1. Corn MON 810	Resistance to corn borer Cry 1A (b) gene from <i>Bacillus Thuringiensis</i>	* 12/03/07	x	x	x	Monsanto
2. Corn Bt 11	Insect protected, herbicide tolerant maize - Bt protein from <i>Bacillus Thuringiensis</i> and PAT protein from <i>Streptomyces viridochromogenes</i>	* 7/22/08	x	x	x	Syngenta
3. Soybean 40-3-2	Resistance to herbicide, R+B19oundup - CP4 EPSSPS from <i>Agrobacterium</i> sp. Strain CP4	* 7/22/08	x	x		Monsanto
4. Corn NK 603	Glyphosate tolerance imparted by the CP4EPSPS coding sequence	* 09/10/08	x	x	x	Monsanto
5. Corn MON 863	Cry3Bb1 for resistance to the Corn root worm, <i>Diabrotica</i> sp.	* 10/07/08	x	x		Monsanto
6. Corn TC 1507	Resistance to certain lepidopterous pests in maize - Cry1F and PAT genes	* 10/07/08	x	x		Pioneer
7. Corn DBT 418	Lepidopteran resistance, phosphino- tricin tolerance - Cry1Ac	* 10/22/08	x	x		Monsanto
8. Canola RT	Glyphosate (Roundup) tolerance	* 10/22/08	x	x		Monsanto

73	- CP4EPSPS					
9. Corn BT 176	Insect protected - Bt protein from Bacillus Thuringiensis and PAT protein from Streptomyces viridochromegenes	* 10/24/08	x	x		Syngenta
10. Corn GA 21	Modified EPSPS for tolerance to glyphosate	*11/20/08	x	x		Monsanto
11. Corn DLL25	Phosphinonoin (PPT) herbicide tolerance specifically glutosinate ammonium	*11/20/08	x	x		Monsanto
12. Corn T25	Phosphinonoin (PPT) herbicide tolerance specifically glutosinate	* 12/05/08	x	x		Bayer Crop Science
13. Cotton 1445	Tolerance to Roundup herbicide	* 12/05/08	x	x		Monsanto
14. Cotton 15985	Resistance to lepidopterous pests	* 12/05/08	x	x		Monsanto
15. Potato Bt (RBBT02-06) and SPBT02-05	Resistance to Colorado potato beetle	* 12/05/08	x	x		Monsanto
16. Potato RBMT 15-101, SEMT 15-02 and SEMT 15-15	Resistance to Colorado potato beetle; resistance to potato virus Y (PVY)	* 12/22/08	x	x		Monsanto
17. Cotton 531	Resistance to lepidopterous pests Cry 1Ac	* 02/05/09	x	x		Monsanto
18. Potato RBMT21-129, RBMT21-350 and RBMT 22-82	Resistance to Colorado potato beetle - CryIIIA coding sequence, Resistance to potato leaf roll virus (PLRV) - PLRV replicase	09/24/04	x	x		Monsanto
19. Sugar beet Event 77	Glyphosate (Round-up) Tolerance	10/21/04	x	x		Monsanto
20. Sugarbeet H7-1	CP4EPSPS coding sequence from Agrobacterium spp. CP4 strain	07/28/05	x	x		Monsanto
21. Cotton MON 88913	Cotton contains the cp4 epsps coding sequence from soil	11/29/05	x	x		Monsanto

	bacterium, Agrobacterium sp. Strain CP4 which confers resistance to glyphosate, the active ingredient in Round Up herbicide					
22. Corn MON 88017	Contains Cry3Bb1 for resistance to the corn rootworm, Diabrotica spp and cp4 epsps for tolerance to glyphosate herbicide	03/08/06	x	x		Monsanto
23. Corn LY038	Contains cordap A coding sequence which is under control of the maize Glb1 promoter that expresses the Cornebacterium glutamicum derived lysine insensitive dihydropicolinate synthase enzyme in the germ to increase the level of lysine in grain for animal feed applications.	05/19/06	x	x		Monsanto
24. Alfalfa J101 and J163		08/09/06	x	x		Monsanto
25. Corn DAS 59122-7	Contains cry34Ab1 and cry35Ab1 from Bacillus thuringiensis w/c confers resistance to certain coleopteran pests such as corn rootworm, Diabrotica sp. And the pat gene from Striptomyces viridochromogenes w/c provides tolerance to glufosinate-ammonium herbicides.	08/09/06	x	x		Pioneer
26. Corn MIR604	Contains modified Cry3A from Bacillus thuringiensis subsp.tenebriones w/c confers resistance to corn rootworm.	10/08/07	x	x		Syngenta
27. Soybean MON 89788	Contains cp4epsps coding sequence from Agrobacterium sp strain. CP4 which confers resistance tolerance to Round up family of ag.herbicides.	11/16/07	x	x		Monsanto
28. Corn 3272	Expresses a synthetic thermostable alpha amylase protein AMY797E that catalyzes the hydrolysis of starch into soluble sugars.	02/07/08	x	x		Syngenta
29. Soybean	Contains pat gene w/c confers	01/23/09	x	x		Bayer

A2704-12	tolerance to glufosinate ammonium herbicide.					CropScience
30. Corn MON89034	Contains 2 genes (cry1A and cry2Ab2) from Bacillus Thuringiensis	04/29/09	x	x		Monsanto

* Renewal

Source of Basic Data: Bureau of Plant Industry